REMARKS

Claims 10-12 and 14-19 are pending in this application. Claims 11 and 12 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Upon entry of these amendments, Claims 10 and 14-19 will be pending. No new matter enters by way of these amendments.

1. Restriction/Election

Applicants acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants reiterate that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 1.

2. Claim Rejections – 35 U.S.C. § 101

Claims 10-12 and 14-19 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Office Action page 3. Applicants respectfully disagree with the Examiner.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "acquiring genes, determining polymorphisms, molecular tags, expression studies, mapping and so forth...." Office Action at page 3. However, the Examiner contends that none of these utilities are "specific and substantial." Applicants respectfully disagree with this assertion.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The instant specification discloses many utilities that satisfy this requirement. One such utility is the use of the claimed nucleic acid molecule in genetic mapping. Specification at page 84, line 4, through page 89, line 2. Another one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 76, line 11 through page 84, line 3. Further uses of the claimed nucleic acid molecules are provided for at page 73, *et. seq.*, under the heading "Uses of the Agents of the Invention."

Applicants maintain that many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are generally applicable to any nucleic acid. Office Action at pages 3-6. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...")[1].

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not

[1] The Examiner appears to assert that *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 U.S.P.Q.2d 1094 (Fed. Cir. 1991) is not applicable simply because the patent at issue in that case related to a "mechanical device and not a laboratory reagent or research tool." Office Action at page 5. A case cannot be disregarded simply because it deals with mechanical arts rather than biological inventions.

only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided

no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner also maintains that the claimed nucleic acid molecules lack utility apparently because "the specification identifies no partial or full open reading frame encoding any protein or fragment thereof and none is apparent." Office Action at page 3. Applicants respectfully submit that the skilled artisan would be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 224, lines 6-12, Table A and the sequence listing) and tools available to practitioners in the art, *e.g.,* BLASTX. Furthermore, neither a partial nor a full open reading frame is necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26

U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 10-12 and 14-19 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

3. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 10-12 and 14-19 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks

utility (*i.e.*, an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

4. Rejection Under 35 U.S.C. §112, 1st Paragraph: Written Description

The Examiner has rejected claims 10-12 and 15-18 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at pages 7-8. Applicants respectfully disagree.

Although the Examiner acknowledges that the specification discloses SEQ ID NO: 1, claims 10-12 and 15-18 allegedly fail to meet the written description requirement because the claims "encompass gene sequences and fragments of sequences of SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, sequences which hybridize and so forth." Office Action at page 7. Applicants respectfully disagree with this contention.

As argued previously, an adequate written description of a genus of nucleic acids, as recited in claims 10-12 and 15-18 may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479,

45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed SEQ ID NO: 2. Applicants have therefore satisfied the *Eli Lilly* test for written description.

Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Nucleic acid molecules falling within the scope of claims 10-12 and 15-18 are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for the claimed invention. Therefore, claims 10-12 and 15-18 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

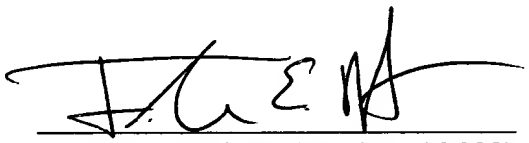
5. Claim Rejections – 35 U.S.C. § 102(b)

Claims 11 and 12 remain rejected under 35 U.S.C. § 102(b) as allegedly "anticipated by GenBank Accession Number D30807 (8 March 1995), as evidenced by Meinkoth et al. (Ana. Biochem. (1984) Vol. 138, pages 267-284)." To facilitate prosecution, claims 11 and 12 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Accordingly, the rejection of claims 11 and 12 under 35 U.S.C. § 102(b) is moot. Applicants respectfully request the 35 U.S.C. § 102(b) rejection be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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